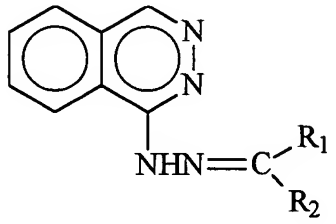
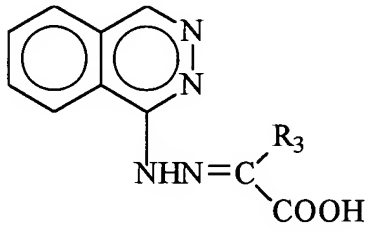
I claim

1. A method of improving the stability of a hydralazine composition during manufacturing or storage comprising coupling an N-protecting group with hydralazine to produce a compound having the formula:



or a compound having the formula:



where R_1 and R_2 are independently H, substituted or unsubstituted branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms; where R_3 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 1 to about 7; and

wherein said N-protecting group is removed from said compound after manufacturing or storage.

2. The method of Claim 1 wherein the N-protecting group is acid-labile and is removed from the hydralazine prior to administration of said compound to a patient.

3. The method of Claim 2 wherein the N-protecting group is plasma-labile and is removed in plasma after administration of said compound to a patient such that the extent and rate of appearance of hydralazine in the plasma is therapeutically similar to that of hydralazine after administration of hydralazine under similar clinical conditions.

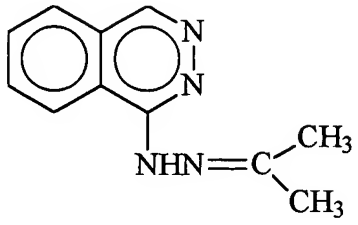
4. The method of Claims 1, 2 or 3 wherein R_1 and R_2 are independently a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

5. The method of Claims 1, 2 or 3 wherein R_2 is H and R_1 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl.

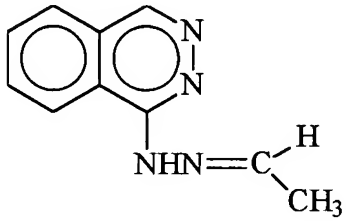
6. The method of Claim 4 wherein R_1 and R_2 are a branched or straight chain alkyl having from about 1 to about 7 carbon atoms.

7. The method of Claim 5 wherein R_1 is a branched or straight chain alkyl having from about 1 to about 7 carbon atoms.

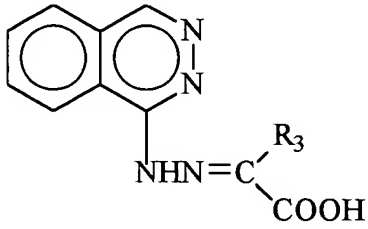
8. The method of Claim 6 wherein said compound has the formula:



9. The method of Claim 7 wherein said compound has the formula:



10. The method of Claim 1 wherein said compound has the formula:



where R_3 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 1 to about 7.

11. The method of Claim 10 wherein R_3 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl.

12. The method of Claim 10 wherein R_3 is a group having the formula $(CH_2)_nCOOH$ where n is from 1 to about 7.

13. The method of Claims 1, 2 or 3 wherein R_1 and R_2 are substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

14. The method of Claims 1, 2 or 3 wherein R_2 is H and R_1 is substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

15. The method of Claim 13 wherein R_1 and R_2 are substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl.

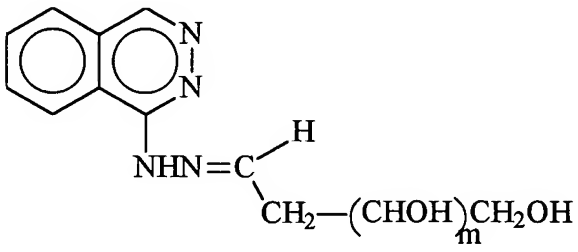
16. The method of Claim 13 wherein R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

17. The method of Claim 14 wherein R_2 is H and R_1 is substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

18. The method of Claim 14 wherein R_2 is H and R_1 is substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl.

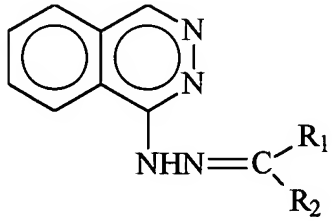
19. The method of Claims 1,2 or 3 wherein R_2 has the formula $CH_2(CHOH)_mCH_2OH$ where m is 2 or 3.

20. The method of Claim 19 wherein said compound has the formula:

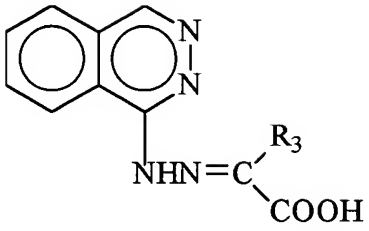


where m is 2 or 3.

21. A compound having the formula:



or a compound having the formula:



where R_1 and R_2 are independently H, branched or straight chain alkyl having from 2 to about 7 ~~carbon~~ atoms, unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl; where R_3 is a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 3 to about 7; with the proviso that when R_1 is H or methyl, then R_2 is a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl.

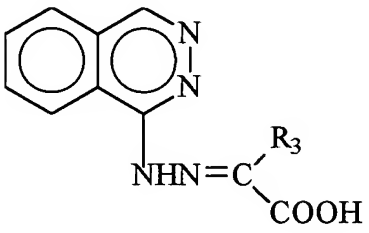
22. The compound of Claim 21 wherein R_1 and R_2 are independently a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms.

23. The compound of Claim 21 wherein R_2 is H and R_1 is a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl.

24. The compound of Claim 23 wherein R_1 and R_2 are a branched or straight chain alkyl having from about 2 to about 7 carbon atoms.

25. The compound of Claim 23 wherein R_1 is a branched or straight chain alkyl having from about 2 to about 7 carbon atoms.

26. The compound of Claim 21 wherein said compound has the formula:



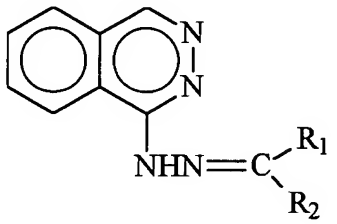
where R_3 is a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 3 to about 7.

27. The compound of Claim 26 wherein R_3 is a branched or straight chain alkyl having from 2 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl.

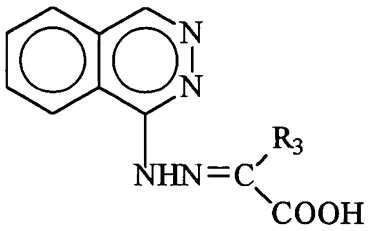
28. The compound of Claim 26 wherein R_3 is a group having the formula $(CH_2)_nCOOH$ where n is from 3 to about 7.

29. The compound of Claim 21 wherein R_1 is substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl.

30. A particulate-free hydralazine composition comprising compound having the formula:



or a compound having the formula:



where R_1 and R_2 are independently H, substituted or unsubstituted branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a

substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms; where R_3 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 1 to about 7 in a pharmaceutically acceptable salt or diluent.

31. The composition of Claim 30 wherein the composition is a liquid pharmaceutical composition and the composition has been stored from about 18 to about 24 months after completion of manufacturing and storage was initiated.

32. The composition of Claim 30 wherein the composition is an injectable formulation and yellow-green particles do not form from 1 to about 2 months after storage 40° C and after about 6 months storage at 25° C.

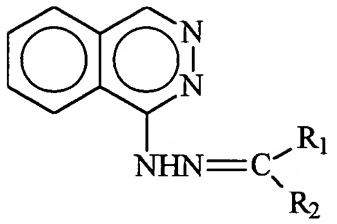
33. The composition of Claim 31 wherein the average number of particles of about 10 microns in the composition does not exceed 6,000.

34. The composition of Claim 31 wherein the average number of particles of about 25 microns in the composition does not exceed 600.

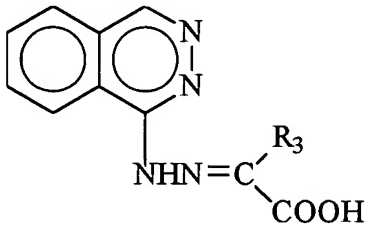
35. The composition of Claim 31 wherein no particles are visible.

36. The composition of Claim 31 wherein the average number of particles of about 10 microns in the composition does not exceed 6,000, the average number of particles of about 25 microns in the composition does not exceed 600, and no particles are visible.

37. A metal ion-free hydralazine composition comprising a compound having the formula:



or a compound having the formula:



where R_1 and R_2 are independently H, branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted cycloalkyl, substituted or unsubstituted aralkyl, substituted or unsubstituted alkylcycloalkyl, lower alkenyl or R_1 and R_2 together form part of a substituted or unsubstituted cycloalkyl having from about 4 of about 7 carbon atoms; where R_3 is a branched or straight chain alkyl having from 1 to about 7 carbon atoms, substituted or unsubstituted aryl, substituted or unsubstituted aralkyl, substituted or unsubstituted cycloalkyl, aralkyl, substituted or unsubstituted alkylcycloalkyl or a group having the formula $(CH_2)_nCOOH$ where n is from 1 to about 7; in a pharmaceutically acceptable salt or diluent; and wherein said compound in said hydralazine composition does not complex with metal ions.

38. The composition of Claim 37 wherein the metal ions are selected from the group consisting of Cu^{+2}, Fe^{+2} and Fe^{+3}.